MEADOX MEDICALS, INC. INVENTION DISCLOSURE

1. GIVE TITLE OF YOUR IDEA: CONFIDENTIAL A.
   Thinly Woven Tubular Prosthesis

2. DESCRIBE YOUR IDEA IN DETAIL AND INCLUDE SKETCH AND FORMULA IF NECESSARY:

   See Attachments

3. STATE ADVANTAGES OVER EXISTING PRODUCTS OR METHODS:

   See Attachments

4. ATTACH AND IDENTIFY COPIES OF ALL KNOWN REFERENCES, DRAWINGS, SKETCHES, DESCRIPTIONS, DATA, ARTICLES, TEXTBOOKS, ETC. (Note: All entries made in Laboratory Notebooks, memoranda, correspondence or similar documentation by author, recipient, date, project number, book number, and page number, if applicable.

   1. Laboratory Notebook #259, pp 8-16, Peter J. Schmitt.
   2. Monthly Project Reports for "Endoprosthesis", Project #010300.
   3. R&D Loom Record Book that contains internal weaving records.
   4. Endoprosthesis Project files - Peter Schmitt, office file cabinet.
   5. Endoprosthesis Project files - Jose Nuñex, office file cabinet.
   6. Laboratory Notebook #303, pp 27-31 and 4, 8-56 Jose Nuñez.
   7. Laboratory Notebook #351, pp 1-17 , Jose Nuñez.
   8. Endoprosthesis Record Book located in R&D office.

5. GIVE NAMES OF OTHER PERSONS FAMILIAR WITH OR WHO HAVE WORKED ON PROJECT: Martin Monestere-MMI, David Lentz-MMI

SIGNATURE(S) OF INVENTOR(S)	DATE	PRINT NAME OF INVENTOR(S)	HOME ADDRESS
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WITNESSED AND UNDERSTOOD BY:

Martin Monestere Signature   Martin Monestere Jr. Print Name   Date:

APPROVED FOR FURTHER PATENT REVIEW:

☐ Yes ☐ No   Date:

☒ Yes ☐ No   David Lentz Vice President   Date:

EXECUTIVE COMMITTEE REVIEW:

☒ Approved for Patentability Opinion   Eleanor Gackstatter President   Date:

☒ Approved for Patent Application   Eleanor Gackstatter President   Date:

☐ Other (explain below)   President   Date:

Comments:

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SUBJECT:

Thinly Woven Tubular Prosthesis

Description: The majority of tubular prosthesis, which are primarily used for the repair of arteries and veins, but not limited to the circulatory system, have wall thicknesses in the range of 0.25-0.75 mm. There are newly emerging surgical procedures that are less invasive than traditional dissection surgery known as endoscopic surgery. Endoscopic surgery is concerned with the repair of internal organs or tissues by entering the body through a natural body opening or through a small incision. In the case of vascular endoscopic surgery, a arteriotomy is made so that a hollow catheter delivery system can be passed through the lumen of the vessel. In order to minimize the size of the incision and trauma to the artery at the entry point, the smallest caliber catheter that can be used is desirable. A graft that is implanted by endoscopic means, therefore, needs to be as thin as possible so that it can be packed inside the lumen of the hollow catheter for delivery into the artery. The thicker the prosthesis is, the larger in diameter the catheter must be. Conventional or traditional vascular prosthesis were not designed for this method of vascular repair. This invention is concerned with producing a vascular prosthesis that has a significantly thinner wall than conventional grafts, yet has the mechanical and physical integrity to sufficiently repair a damaged or diseased vascular vessel. The thin wall grafts are not limited to endoscopic surgical placement techniques. These grafts can be implanted by conventional surgical means. It allows them to be used in a wider range of applications.

The invention is based upon weaving technology to produce a thin wall, high strength polyester graft. The woven structure was chosen, because it is among the most efficient textile fabrics to deliver the greatest performance with the least amount of material. The fabric is made up of two sets of yarns that are orthagonally opposed to one another. Unlike warp knit fabrics, there are only two layers of yarn through the thickness of the fabric. The simplest warp knit fabric, tricot, is three yarns thick. It is also easier to design grafts with lower porosity with less thickness using woven fabrics than warp or weft knitted fabrics. The woven graft of the invention would be no greater than 0.25 mm thick. There is no minimum limit, provided that sufficient burst strength, tear strength, and porosity are achieved. The woven graft would be composed of yarns that are no greater than 70 denier. Yarns of this denier will allow a graft of 0.25 mm or less to be produced.

The graft can be composed of flat yarns, twisted yarns, textured yarns, pre-shrunk yarns, or combinations thereof to provide the characteristics desired. The yarns can be made of PET polyester, PTFE, polyethylene, polypropylene, or some other biomedical acceptable polymer. The higher the specific strength of the fiber, the less that would be required. Higher tenacity fibers can be used to produce thinner grafts.

WOVEN CONSTRUCTIONS

Example 1: Plain Weave - Tubular Fabric
- Warp Yarn - 40 den./27 filament flat polyester
- Fill Yarn - 40 dens./27 filament textured polyester
- Ends per inch - 128 per layer
- Picks per inch - 88 per layer
- Wall thickness - 0.08 mm

INVENTOR DATE

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Thinly Woven Tubular Prosthesis

Example 2: Plain Weave - Tubular Fabric
- Warp Yarn - 50 den./48 filament flat polyester
- Fill Yarn - 50 dens./48 filament flat polyester
- Ends per inch - 188 per layer
- Picks per inch - 88 per layer
- Wall thickness - 0.12 mm

After weaving, the grafts would be scoured to remove dirt, oil, processing agents, etc. The material could then be heat-set to stabilize the product. Heat-setting can be accomplished in a steam autoclave, convection oven, etc. The tubular fabric can be heat-set on smooth mandrels to precisely set the diameter and to remove creases and wrinkles. The grafts can be crimped to impart longitudinal compliance and radial support, if necessary.

A primary advantage of thin wall grafts is that the crimp imparted can be of very high frequency and low amplitude. Because the grafts are considerably thinner than traditional grafts, they can be crimped with much finer crimps. The thin wall and increased flexibility make this possible. The advantage of this finer crimp is that there is less of a difference between the minor and major diameters. There is less area for thrombus, plaque, etc. to build up. It also can reduce the amount of turbulence created in the vessel due to the irregular profile of the graft wall.

HEAT-SETTING AND CRIMPING

Example 1 Heat-set method - convection oven
- Temperature - 175°C
- Time - 15 minutes
- Mandrels - smooth

Example 2 Heat-set method - steam autoclave
- Temperature - 122°C
- Time - 2 minutes
- Mandrels - smooth

Example 3 Crimping method - circular crimping wheel
- Temperature - 175°C
- Pitch - 10 crimps/cm
- Depth - 0.25 mm

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The grafts can also contain a radiopaque guideline (marker). Guidelines are typical present on grafts to assist the surgeon in preventing the graft from becoming twisted during surgery. A radiopaque guideline could be used to help the surgeon visualize the graft after it has been implanted. The guideline would be invisible to X-rays, which would allow it to appear in post-operative examinations. Radiopaque guidelines can also be used to readily see if a graft has dilated or collapsed without having to inject radiopaque dyes into the circulatory system of the patient. The radiopaque guideline could also be used during the time of endoscopic placement of a graft to assist in the positioning of the graft.

The radiopaque guideline can be made from a metallic fiber, such as stainless steel, titanium, etc.; from a polymeric fiber, such as polyester, polyethylene, etc. filled with radiopaque particles, such as stainless steel, titanium, gold, barium sulfate, etc.; or from a polymeric fiber coated or plated with a radiopaque substance such as gold, silver, etc.

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